EXHIBIT S50 TO DECLARATION OF STEPHEN G. SCHWARZ IN SUPPORT OF PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

EDWARD BAKER and JACK MILLER, on behalf of themselves and all others similarly situated,	:	1:16-cv-00260
Plaintiffs,	:	Hon. John E. Jones III
v.	:	
SORIN GROUP DUETSCHLAND GMBH and SORIN GROUP USA, INC.,	:	
Defendants,	:	

[UNDER SEAL]

MEMORANDUM & ORDER

October 23, 2017

Presently pending before the Court is the Plaintiffs' motion for class certification.[1] (the "Motion") (Doc. 60). Named Plaintiffs Edward Baker and Jack Miller ("Plaintiffs") seek class certification pursuant to Federal Rule of Civil Procedure 23 and filed the instant Motion on April 4, 2017, along with a brief in support. (Doc. 60, att. 2). Defendants Sorin Group Deutschland GMBH and Sorin Group USA, Inc. (collectively, "Defendants" or "Sorin") filed a brief in opposition on May 8, 2017. (Doc. 67). Plaintiffs filed a brief in reply on May 17, 2017. (Doc.

[1] Also pending is Defendants' motion for oral argument on the Plaintiffs' motion for class certification. (Doc. 70). As reflected in this memorandum and order, oral argument was unnecessary for this Court to render a decision on the motion for class certification. As such, the motion for oral argument is denied.

72, att. 2). The Motion is therefore ripe for our review. For the reasons that follow, the Motion shall be granted.

I. BACKGROUND

Edward Baker and Jack Miller commenced this action by filing a complaint on February 12, 2016. (Doc. 1). Plaintiffs submitted an Amended Complaint on March 21, 2016, asserting a medical monitoring claim and a declaratory judgment claim against the Sorin Defendants and their holding company. (Doc. 8). On September 29, 2016, we granted the holding company's motion to dismiss for lack of personal jurisdiction. (Doc. 45). We denied the Sorin Defendants' motion to dismiss for failure to state a claim in its entirety on October 11, 2016. (Doc. 46). Defendants thereafter submitted an answer to the Amended Complaint. (Doc. 49). Now before the Court is Plaintiffs' motion for class certification. (Doc. 60).

Plaintiffs allege that the putative class was exposed to nontuberculous mycobacterium ("NTM") through a Sorin 3T Heater-Cooler System ("3T System") used to regulate their blood temperature during open heart surgeries at WellSpan York Hospital ("WellSpan") and Penn State Milton S. Hershey Medical Center. ("Hershey"). Named Plaintiffs and proposed class representatives both underwent open-heart surgery at WellSpan and received notification letters warning of potential exposure to NTM. (Doc. 60, Ex. C) (Doc. 60, Ex. F, ¶ 9).

Plaintiffs seek class certification for the following group of people:

All individuals who underwent open heart surgery:

1. At WellSpan York Hospital between October 1, 2011 and July 24, 2015; or
2. Penn State Milton S. Hershey Medical Center between November 5, 2011 and November 5, 2015; and
3. Who are currently asymptomatic for NTM infection.

(Doc. 60, att. 2, pp. 1-2). The purported class excludes any individual who suffered actual injury from an NTM infection from surgery at WellSpan or Hershey, as this action is for medical monitoring and declaratory judgment claims. The following is a brief overview of the facts giving rise to the claims against the Sorin Defendants.

On October 26, 2015, WellSpan notified approximately 1,300 open-heart surgery patients of possible exposure to NTM during open-heart surgeries performed between October 1, 2011 and July 24, 2015. (Doc. 60, Ex. A). The WellSpan notification indicated that NTM escaped from heater-cooler devices used during open-heart surgery to regulate blood temperature. (*Id.*). On November 10, 2015, Hershey notified approximately 2,300 open-heart surgery patients of possible exposure to the same bacteria from its heater-devices. (Doc. 60, Ex. B).

According to the Pennsylvania Department of Health, NTM are commonly found in soil and water, including tap water. (Doc. 60, Ex. G, p. 1). NTM are usually not harmful, but can cause infections in patients who have had invasive procedures and weakened immune systems. (*Id.*). Patients do not come into direct contact with the water in heater-cooler systems during open-heart surgery, but

NTM in the machine can potentially be transmitted through aerosolization of the contaminated water in the device and enter the body through breathing or through the skin. (*Id*.). The Department of Health warned that NTM grows slowly and it can take several years before people with infections are diagnosed. (Doc. 60, Ex. G, p. 2). In addition, the Department of Health expressed the importance for potentially exposed individuals to be aware of the symptoms of NTM infection and follow up with their health providers. (*Id*., at p. 1). The Department of Health stated its belief that all patients who had open heart surgeries requiring cardiopulmonary bypass at WellSpan between October 1, 2011 and July 24, 2015, as well as those at Hershey from November 5, 2011 and November 5, 2015, could have been exposed to NTM. (*Id*., at pp.2-3).

The Food and Drug Administration ("FDA") issued an advisory on October 13, 2016 regarding NTM and the connection to heater-cooler systems. (Doc. 60, Ex. H). The advisory warned that a specific type of NTM called *M. chimaera* has been associated with Sorin's 3T Heater-Cooler System. (*Id*.). The Sorin 3T System was approved by the FDA on June 6, 2006 as a Class II medical device following the 510(k) process, which allows the FDA to approve a device following a determination that it is equivalent to a device already placed on the market. (Doc. 67, DEF-1). The FDA issued a recommendation for health care facilities to "[i]mmediately remove from service any heater-cooler devices, accessories, tubing,

and connectors that have tested positive for *M. chimaera* or have been associated with known *M. chimaera* patient infections at your facility." (Doc. 60, Ex. H, p. 3).

The FDA issued an update on October 13, 2016 warning that Sorin 3T Systems manufactured prior to September 2014 were at risk for *M. chimaera* exposure. (Doc. 60, Ex. H). The Sorin Defendants followed this update with their own on October 13, 2016, identifying the serial numbers for the 3T Systems manufactured prior to September 2014. (Doc. 60, Ex. K). WellSpan had three Sorin 3T Systems and Hershey had five. (Doc. 60, Ex. CC). Plaintiffs attached at Exhibit CC a list of United States customers that purchased Sorin 3T Systems, which includes the serial numbers for all eight of the 3T Systems at issue.[2] (*Id.*). The serial numbers for the Hershey and WellSpan 3T Systems fell into the category of devices potentially exposed to *M. chimaera*.

Both parties have submitted copious documentary exhibits regarding the 3T Systems and *M. chimaera* exposure, including research studies, FDA documents, Department of Health Advisories, internal Sorin documents and studies, and scientific literature on the topic.

[2] Hershey had five 3T Systems with the serial numbers 16S10918, 16S11094, 16S11514, 16S11958, and 16S14596. WellSpan had three 3T systems with the serial numbers 16S11621, 16S12831, and 16S12832. (Doc. 60, Ex. CC, pp. 35, 42).

II. LEGAL STANDARD

A federal court may only certify a class for litigation if it determines, after a "rigorous analysis," that the party seeking class certification has met all of the prerequisites of Rule 23. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 309 (3d Cir.2008) (citing *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 161 (1982); *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 615 (1997); *Beck v. Maximus*, 457 F.3d 291, 297 (3d Cir.2006)). "Factual determinations necessary to make Rule 23 findings must be made by a preponderance of the evidence." *Hydrogen Peroxide*, 552 F.3d at 320. Thus, the "requirements set out in Rule 23 are not mere pleading rules," and the class certification inquiry "requires a thorough examination of the factual and legal allegations." *Id*. at 316; *Newton v. Merrill Lynch, Pierce, Fenner & Smith*, 259 F.3d 154, 166 (3d Cir.2001). "An overlap between a class certification requirement and the merits of a claim is no reason to decline to resolve relevant disputes when necessary to determine whether a class certification requirement is met." *Hydrogen Peroxide*, 552 F.3d at 316.

To obtain class certification under Rule 23, Plaintiff must satisfy both the conjunctive requirements of subpart (a) and one of the requirements of subpart (b). FED. R. CIV. P. 23; *In re Schering Plough Corp. ERISA Litigation*, 589 F.3d 585, 596 (3d Cir.2009). The touchstones of subpart (a) are: "(1) numerosity (a 'class [so large] that joinder of all members is impracticable'); (2) commonality ('questions

of law or fact common to the class'); (3) typicality (named parties' claims or defenses 'are typical ... of the class'); and (4) adequacy of representation (representatives 'will fairly and adequately protect the interests of the class')." *Amchem Prods*., 521 U.S. at 613, 117 S.Ct. 2231. Plaintiffs here seek class certification pursuant to Rule 23(b)(2), which requires a showing that "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." FED. R. CIV. P. 23(b)(2).

III. DISCUSSION

To start, we make explicit that "Plaintiffs' burden is not to prove the elements of their claim, but to show that those elements are capable of proof through evidence that is common to the class." *In re Actiq Sales & Mktg. Practices Litig*., 307 F.R.D. 150, 163 (E.D. Pa. 2015). We start with this principle because, much like their arguments at the motion to dismiss stage, Defendants spend considerable time arguing the merits of Plaintiffs' claims. There is certainly overlap between issues of class certification and the merits of the claims, but we only consider disputes on the merits to the extent that they inform upon the certification determination. *Hydrogen Peroxide*, 552 F.3d at 316. Having laid the proper foundation, we now will consider each requirement of Rule 23 that Plaintiffs must satisfy to attain class certification.

A. Numerosity

Rule 23 states that numerosity is satisfied when "the class is so numerous that joinder of all members is impracticable." FED R. CIV. P. 23(a)(1). Defendants offer no argument to dispute that Plaintiffs have satisfied the numerosity requirement, and with good reason – our Court of Appeals instructs that "[n]o minimum number of plaintiffs is required to maintain a suit as a class action, but generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met." *Stewart v. Abraham*, 275 F.3d 220, 226–27 (3d Cir. 2001). Plaintiffs attach two exhibits to demonstrate that the purported class meets the numerosity requirement of Rule 23(a)(1). The first is an affidavit from Alan L. Breechbill, the Executive Director of Hershey, that states Hershey sent letters to 2,289 patients to warn of exposure to NTM through cardiac procedures. (Doc. 60, Exhibit E). The second is the WellSpan press release that states that approximately 1,300 patients were notified of potential exposure to NTM at their hospital. (Doc. 60, Exhibit A). Considering the large size of the putative class, we find that Plaintiffs have satisfied their burden to meet the first prong of Rule 23(a).

B. Commonality

"A putative class satisfies Rule 23(a)'s commonality requirement if the named plaintiffs share at least one question of fact or law with the grievances of

the prospective class." *Rodriguez v. Nat'l City Bank*, 726 F.3d 372, 382 (3d Cir. 2013) (internal quotation marks omitted). Defendants very reasonably do not offer argument that the putative class fails the commonality requirement of Rule 23(a)(1). Plaintiffs provided a list of "just a few common questions," which we find useful in demonstrating that the class meets the commonality requirement:

1. Whether the 3T is defective in design and/or manufacture;

2. On defective design, whether reasonable alternative designs existed that would have reduced or eliminated the risk of NTM infections with the 3T;

3. Whether the 3T's IFUs failed to advise users of effective cleaning and disinfection procedures;

4. Whether Defendants failed to timely warn users of the potential for bacterial colonization and aerosolization in 3Ts;

5. Whether the Class was exposed to *M. Chimaera* at greater than normal background levels;

6. Whether *M. Chimaera* is a proven hazardous substance;

7. Whether Defendants negligently caused the Class to be exposed to *M. Chimaera*; and

8. Whether the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

(Doc. 60, att. 2, p. 15). Commonality is plainly satisfied.

C. Typicality

Typicality requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." FED. R. CIV. P. 23(A)(3). The

typicality requirement ensures that "the class representatives are sufficiently *similar* to the rest of the class—in terms of their legal claims, factual circumstances, and stake in the litigation—so that certifying those individuals to represent the class will be fair to the rest of the proposed class." *In re Schering Plough Corp. ERISA Litig*., 589 F.3d 585, 597 (3d Cir. 2009). The Third Circuit has offered "three distinct, though related, concerns" to consider in assessing typicality:

> (1) the claims of the class representative must be generally the same as those of the class in terms of both (a) the legal theory advanced and (b) the factual circumstances underlying that theory; (2) the class representative must not be subject to a defense that is both inapplicable to many members of the class and likely to become a major focus of the litigation; and (3) the interests and incentives of the representative must be sufficiently aligned with those of the class.

Id., at 599. Defendants argue that Baker and Miller's claims are atypical of the class for two reasons: both underwent surgery at WellSpan and both had surgery in March 2015, after Defendants learned about the risk of *M. chimaera* infections. (Doc. 67, p. 33).

We note that "[c]omplete factual similarity is not required; just enough factual similarity so that maintaining the class action is reasonably economical and the interests of the other class members will be fairly and adequately protected in their absence." *In re Schering Plough Corp. ERISA Litig.*, 589 F.3d at 598. "[F]actual differences between the proposed representative and other members of

the class do not render the representative atypical if the claim arises from the same event or practice or course of conduct that gives rise to the claims of the class members." *Id*. (internal quotation omitted).

Defendants argue that Baker and Miller are inadequate class representatives because they both underwent surgery at WellSpan and "cannot provide the evidence necessary to advance the Hershey plaintiffs' claims." (Doc. 67, p. 33) "For example, Baker could not testify regarding what Hershey patients received from the Hershey NTM clinic." (*Id*.). For support of this contention, Defendants cite two district court cases that are highly distinguishable.[3] Whether Baker and Miller could personally testify about the Hershey claims is immaterial; the typicality requirement asks whether "the incentives of the plaintiffs are aligned with those of the class." *Baby Neal v. Casey*, 43 F.3d 48, 55 (3d Cir.1994). Baker and Miller's claims arise out of the same alleged course of conduct by the Defendants – exposure to NTM through a 3T System as a result of the Defendants' negligence. The only pertinent factual difference is the hospital at which Baker and Miller were allegedly exposed: "[t]hat fact may distinguish [them] from other class

[3] Baker and Miller have one factual difference from the Hershey class members – they underwent surgery at WellSpan. Defendants cite to *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279, 310 (N.D. Ohio 2007), where the court considered "the great variety of products, manufacturers, warnings, employers, and workplaces involved." Defendants also cite to *Martin v. Home Depot U.S.A., Inc.*, 225 F.R.D. 198, 201 (W.D. Tex. 2004), where the case concerned an allegedly defective wood product and "treated wood is not like other consumer products which are essentially interchangeable with respect to their appearance, use and composition." We have no indication that the 3T Systems used at WellSpan and Hershey would vary in that way and thus neither case is persuasive.

members, but it does not prejudice [their] ability to protect absent class members' interests." *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 599 (3d Cir. 2012).

Defendants next argue that Baker and Miller cannot satisfy typicality because they had surgery in March 2015; "[t]heir claims are thus not typical of patients who had surgery earlier in the class period when the risk of *M. chimaera* and aerosolization was un-hypothesized, or of patients who had surgery after Defendants issued new cleaning instructions in June 2015." (Doc. 67, p. 33). On its face, this argument presents a colorable issue of typicality because it suggests that there may be different defenses to Baker and Miller's claims than to other class members; as one of the elements of a medical monitoring claim is that the exposure was caused by the Defendants' negligence, Plaintiffs must prove at trial that the Defendants' actions were unreasonable in light of what Defendants knew regarding the risk of NTM at the time of its alleged actions or omissions. *In re Fosamax Prod. Liab. Litig.*, 248 F.R.D. 389, 399 (S.D.N.Y. 2008). As such, Defendants argue that the timing of each class members' alleged exposure is highly relevant and negates typicality of Baker and Miller's cases. (Doc. 67, p. 33).

However, Defendants do not provide concrete examples of how their defenses would differ for different class members. Plaintiffs, on the other hand, point to evidence to support that the difference in timing of each class members' surgery will *not* present typicality problems. (Doc. 72, att. 1, pp. 13-15). Plaintiffs

argue that the legal theory of the class is that "Defendants **have yet to release an <u>effective</u> cleaning protocol for the 3T**," making the timing of each surgery irrelevant because the Defendants were negligent throughout the class period. (*Id*., at pp. 13-14) (emphasis in original). In support of their theory, Plaintiffs point to studies that conclude Defendants' updated maintenance recommendations were inadequate. (Doc. 60, Ex. T) (study dated October 2016 concludes, "[o]ur findings challenge the effectiveness of the HCU manufacturer's maintenance recommendations . . .") (Doc. 60, Ex. S) ("results following decontamination protocols supplied by the manufacturer showed that these decontamination methods were inadequate.").

While Defendants may intend to present evidence negating negligence during different times, Plaintiffs intend to present common evidence that Defendants were negligent during the entire class period. Considering that the Third Circuit has "set a 'low threshold' for typicality", we find that Plaintiffs have satisfied their burden of demonstrating typicality for the purported class. *In re Nat'l Football League Players Concussion Injury Litig*., 821 F.3d 410, 428 (3d Cir.), as amended (May 2, 2016), cert. denied sub nom.

D. Adequacy

Rule 23(a)(4) requires that plaintiffs must "fairly and adequately protect the interests of the class." FED. R. CIV. P. 23(A)(4). "Adequate representation depends

on two factors: (a) the plaintiff's attorney must be qualified, experienced, and generally able to conduct the proposed litigation, and (b) the plaintiff must not have interests antagonistic to those of the class." *Wetzel v. Liberty Mut. Ins. Co.*, 508 F.2d 239, 247 (3d Cir. 1975). Defendants do not question the adequacy of Plaintiffs' counsel, but argue that Plaintiffs Baker and Miller are inadequate class representatives for two reasons: first, they "have already received the monitoring they request" and second, neither has sustained any damages. (Doc. 67, p. 34).

Baker testified that he attended an NTM clinic through WellSpan and visits his primary care physician for follow up care. (Doc. 67, DEF-29, 92:5-99:4, 89:12-13). Miller also testified that he attended the WellSpan NTM clinic, and that he receives follow up care from his regular physicians. (Doc. 67, DEF-30, 38:3-15, 83:24-86:6). We fail to understand how these facts render the Plaintiffs inadequate class representatives. That the Plaintiffs have already received some monitoring care does not mean that they will not continue to undergo monitoring for potential NTM infection; the purpose of this action is to place the costs of future monitoring on the Defendants. It is likely that many putative class members will have undergone initial monitoring once they received their letters from WellSpan and Hershey regarding potential NTM exposure. That Baker and Miller have already

received some medical monitoring does not pose any conflict of interest with other class members who have not.[4]

Defendants also argue that Plaintiffs are inadequate because they have not sustained any damages; WellSpan has covered all costs related to their monitoring thus far. (Doc. 67, p. 35). Again, we fail to see the significance in this argument. The medical monitoring claim seeks to establish a fund to provide future medical monitoring, not to compensate past medical costs. Therefore, lack of damages is immaterial.

We see no reason why Plaintiffs and their counsel would be inadequate representatives of the putative class. As discussed with the typicality requirement, Baker and Miller sit in a substantially similar position as all other putative class members and Defendants have not pointed to any conflict of interest that would suggest they could not fairly and adequately represent the putative class.

E. Rule 23(b)(2)

Having found that Plaintiffs satisfy each requirement of Rule 23(a), we move next to Rule 23(b). Plaintiffs seek class certification pursuant to Rule

[4] Defendants cite to *In re Bacol Products Litigation*, 218 F.R.D. 197 (D. Minn. 2003) for the proposition that "[i]n medical monitoring cases, plaintiffs who have already received the requested monitoring are not adequate representatives of those who have not received any medical testing." (Doc. 67, p. 34). This case does not stand for what the Defendants posit. While the court did recognize that the named representatives "already received the tests advocated," the much more pertinent distinction between the representatives and the class was that the representatives alleged actual injury along with medical monitoring. *Baycol*, 218 F.R.D. at 211.

23(b)(2), which provides for certification where "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." FED. R. CIV. P. 23(b)(2). "Two showings must therefore be made in order to proceed under Rule 23(b)(2)." *Barabin v. Aramark Corp.*, 210 F.R.D. 152, 160 (E.D. Pa. 2002), *aff'd*, No. 02-8057, 2003 WL 355417 (3d Cir. Jan. 24, 2003). "First, the complaint must seek relief which is predominantly injunctive or declaratory . . . [and] [s]econd, plaintiffs must complain that defendants acted or refused to act on grounds generally applicable to the class." *Id.*

Defendants argue that the putative class is inappropriate for certification under Rule 23(b)(2) because it does not seek primarily injunctive relief and because the class is not sufficiently cohesive. (Doc. 67, pp. 15, 19). We will address each argument in turn.

1. Type of Relief

Plaintiffs argue that their "request for medical monitoring is properly treated as injunctive in nature because rather than compensatory damages, Plaintiffs and the Class seek the establishment of a court-supervised medical monitoring program that provides periodic medical examination to screen for NTM infections." (Doc. 60, att. 2, p. 20). In order to determine whether this type of prayer for relief is

appropriate for certification under Rule 23(b)(2), we must analyze the current precedential framework.

Initially, we note that medical monitoring is a claim under Pennsylvania law and the Pennsylvania Supreme Court has endorsed awarding medical monitoring damages as a trust fund, though it did so without addressing class certification. *Redland Soccer Club, Inc. v. Dep't of the Army & Dep't of Def. of the U.S.*, 696 A.2d 137, 148 (1997). In 1998, the Third Circuit reviewed a case concerning certification of a Pennsylvania medical monitoring claim seeking damages as a trust fund under Rule 23(b)(2) in *Barnes v. Am. Tobacco Co.*, 161 F.3d 127 (3d Cir. 1998). *Barnes* concerned class certification for a medical monitoring claim against major American tobacco companies. 696 A.2d at 130. The Court ultimately affirmed the district court's decertification of the class due to the multitude of individual issues in the case, and thus did not offer comment or guidance on whether a medical monitoring claim seeking a trust fund could ever qualify as injunctive relief under Rule 23(b)(2). Instead, the Court simply quoted extensive portions of the district court opinion.

The district court held that "it is apparent that relief requested under a medical monitoring claim can be either injunctive or equitable in nature." *Id.*, at 132. In reaching this conclusion, the district court cited favorably to Judge Speigel's articulation of the distinction between a medical monitoring claim

seeking monetary relief and one seeking injunctive relief in *Day v. NLO, Inc*., 144 F.R.D. 330, 335-3336 (S.D. Ohio 1992), *rev'd on other grounds*, 5 F.3d 154 (6th Cir. 1993). Judge Spiegel explains:

> Relief in the form of medical monitoring may be by a number of means. First, a court may simply order a defendant to pay a plaintiff a certain sum of money. The plaintiff may or may not choose to use that money to have his medical condition monitored. Second, a court may order the defendants to pay the plaintiffs' medical expenses directly so that a plaintiff may be monitored by the physician of his choice. Neither of these forms of relief constitute injunctive relief as required by Rule 23(b)(2).
>
> However, a court may also establish an elaborate medical monitoring program of its own, managed by court-appointed court-supervised trustees, pursuant to which a plaintiff is monitored by particular physicians and the medical data produced is utilized for group studies. In this situation, a defendant, of course, would finance the program as well as being required by the Court to address issues as they develop during the program administration. Under these circumstances, the relief constitutes injunctive relief as required by Rule 23(b)(2).

Day, 144 F.R.D. at 335-336. From this, the district court concluded,

> The dispositive factor that must be assessed to determine whether a medical monitoring claim can be certified as a Rule 23(b)(2) class is-what type of relief do plaintiffs actually seek. If plaintiffs seek relief that is a disguised request for compensatory damages, then the medical monitoring claim can only be characterized as a claim for monetary damages. In contrast, if plaintiffs seek the establishment of a court-supervised medical monitoring program through which the class members will receive periodic medical examinations, then plaintiffs' medical monitoring claims can be properly characterized as claim seeking injunctive relief.

Barnes, 161 F.3d at 132 (citing *Arch v. Am. Tobacco Co*., 175 F.R.D. 469, 484 (E.D. Pa. 1997). The Court in *Barnes* provided block quotes to each of these

references by the district court, but limited its own discussion regarding Rule 23(b)(2) to the general requirements that the class be cohesive and that too many individual issues will render a class inappropriate for certification. *Id*., at 142-143.

In 2011, the Supreme Court decided *Wal-Mart Stores, Inc. v. Dukes, et. al*, 564 U.S. 338 (2011), reversing certification of a class alleging Title VII discrimination and seeking awards of backpay under Rule 23(b)(2). *Dukes*, 564 U.S. at 342. *Dukes* was highly distinguishable from our case, as the Title VII claims involved abundant individual issues, including each relevant employment decision, the reasons for those decisions, and individual calculation of each class member's backpay. *Id*. at 352. The Court did, however, provide relevant dicta in its analysis of certification under Rule 23(b)(2).

> In other words, Rule 23(b)(2) applies only when a single injunction or declaratory judgment would provide relief to each member of the class. It does not authorize class certification when each individual class member would be entitled to a different injunction or declaratory judgment against the defendant. Similarly, it does not authorize class certification when each class member would be entitled to an individualized award of monetary damages.

Id., at 360. The Court recognized a Fifth Circuit holding that permitted certification when a class seeks monetary relief that is "incidental to requested injunctive or declaratory relief." *Id*., at 365-366 (citing *Allison v. Citgo Petroleum Corp.*, 151 F.3d 402, 415 (5th Cir. 1998).The Fifth Circuit defined "incidental relief" as "damages that flow directly from liability to the class as a whole on the

claims forming the basis of the injunctive or declaratory relief." *Allison*, 151 F.3d at 415. It reasoned that such "incidental damage should not require additional hearings to resolve the disparate merits of each individual's case; it should neither introduce new substantial legal or factual issues, nor entail complex individualized determinations." *Id*. Unfortunately for our purposes, the Supreme Court chose not to pass judgment on the merits of the Fifth Circuit's interpretation because the facts in *Dukes* so clearly did not fit that standard. *Dukes*, at 366.

Following *Dukes*, the Third Circuit questioned whether medical monitoring claims seeking damages through a fund could qualify under Rule 23(b)(2), but likewise did not offer a conclusion. *Gates v. Rohn and Haas Co*., 355 F.3d 255 (3d Cir. 2011). In *Gates*, the Third Circuit affirmed the district court's denial of class certification in a medical monitoring claim against a chemical company. *Id*., at 258. The Court recognized that "[i]f the plaintiffs prevail, class members' regimes of medical screenings and corresponding cost will vary individual by individual," but chose not to determine whether that variance would remove the claim from the realm of Rule 23(b)(2) class certification in light of *Dukes*. *Id*., at 263. The particular case concerned many individual issues regarding exposure levels, risk of disease, and property damage, and thus certification was denied "for reasons apart from the monetary nature of plaintiffs' claims." *Id*., at 263.

These cases leave us with no conclusive guidance on whether a medical monitoring claim seeking a court-supervised fund qualifies as injunctive relief under Rule 23(b)(2). *Barnes*, *Dukes*, and *Gates* all concerned matters that abounded with individualized issues, preventing any dispositive analysis into the damages aspect of the rule. In consideration of all of the dicta provided in these cases, as well as the Fifth Circuit's persuasive reasoning from *Allison*, we now hold that a medical monitoring claim such as this, where the putative class seeks establishment of a court-supervised fund financed by the defendants to provide future medical monitoring care, [5] is predominantly injunctive in nature and thus is eligible for class certification under Rule 23(b)(2).

Our holding is premised on the unique characteristics of this medical monitoring case and follows the reasoning of Judge Spiegel in *Day*, 144 F.R.D. at 335-336, and the district court in *Arch*, 175 F.R.D. at 484. The relief in a medical monitoring action, and the relief that the putative class seeks here, is provision of

[5] Defendants argue that Plaintiffs' claim of seeking a court-supervised fund "contradicts their own complaint" and is a "belated request" that "lacks specificity." (Doc. 67, pp. 16-17). We disagree with Defendants that Plaintiffs' request for a court-supervised fund contradicts their complaint. Plaintiffs' amended complaint contains a list of prayers for relief, including "[a] declaration that the Defendants are financially responsible for implementing and maintaining a fund for the medical monitoring of Plaintiffs and Class Members." (Doc. 8, p. 21). Because of liberal pleading standards, we also disagree with the notion that Plaintiffs would have to include specifics on the formulations of the fund in their complaint. This argument regarding specificity of Plaintiffs' prayer for a fund is premature at this stage. The prayer for relief also includes "[a]n award to Plaintiff and Class Members of damages, costs and disbursements in this action." (Id.). Because Rule 23(b)(2) only allows for certification of claims seeking predominantly injunctive relief, we explicitly exclude from the class claims any prayer for individual damages, costs, and disbursements.

future periodic medical examinations to promote early detection a latent disease. Where, as here, the alleged exposure is the same for each class member, this type of relief "can be properly characterized as invoking the court's equitable powers." *Arch*, 175 F.R.D. at 484. Unlike claims for compensatory damages, the Court need not analyze and compute individual claims for monetary relief in conjunction with liability; instead, one unified order forming a fund financed by the Defendants would provide relief to each class member. As the district court in *Arch* held, we find this to be "paradigmatic request for injunctive relief under a medical monitoring claim." 175 F.R.D. at 484.

To explain using the Supreme Court's language in *Dukes*, establishment of a court-supervised fund for medical monitoring would be "a single injunction or declaratory judgment [that] would provide relief to each member of the class." *Dukes*, 564 U.S. at 360. It does not create the situation *Dukes* warned about where "each individual class member would be entitled to a different injunction or declaratory judgment" or "an individualized award of monetary damages." *Id*., at 360.

This matter is particularly unique in its lack of individualized issues, discussed further in the next section regarding cohesiveness. Plaintiffs intend to prove exposure for each class member by demonstrating that a defective 3T System was used during their open-heart surgeries. Beyond that, Plaintiffs'

evidence to show that NTM is a hazardous substance, that Defendants were negligent, that exposed patients have an increased risk of developing disease, and that medical monitoring is necessary do not concern any individualized issues at all. This is not a case where a class member's use of or exposure to the allegedly defective product varies between individuals, causing each member's risk for infection and need for monitoring to vary as well. While the costs for each class member's medical monitoring may certainly differ depending on that individual's exhibited symptoms and other medical factors, those variances are properly characterized as incidental to the main form of equitable relief.

The Fifth Circuit noted in *Alison* that one way to determine if the relief sought is primarily injunctive in nature is to ask whether the damages are "capable of computation by means of objective standards and not dependent in any significant way on the intangible, subjective differences of each class member's circumstances." 151 F.3d at 415. Calculation of incidental damages should "not require additional hearings to resolve the disparate merits of each individual's case; it should neither introduce new and substantial legal or factual issues, nor entail complex individualized determinations." *Id*. Plaintiffs' medical monitoring claim is a quintessential fit for these standards. It would not require any court calculation into individual damages, and would allow for the creation of a fund with objective, class wide standards for the expenditure of medical monitoring procedures. Each

individual class member may receive different sized "awards" in the sense that the care required for each person may be different based on physician opinion and individual medical factors, but those variances have no effect on the order of relief as a whole.

For all of these reasons, we find that Plaintiffs' claim for medical monitoring and prayer for a medical monitoring fund financed by the Defendants is certifiable under Rule 23(b)(2). We note that Defendants also offer argument that Plaintiffs' Count Two for declaratory judgment is unfit for certification under Rule 23(b)(2), but only because of its intertwinement with the medical monitoring claim and its prayer for a fund. (Doc. 67, p. 31). Because we find that the medical monitoring claim is appropriately certified as predominately injunctive or declaratory relief under the rule, Defendants argument against certification of Count Two lacks merit. A declaratory judgment claim fits squarely within Rule 23(b)(2) and is appropriate for certification.

2. Cohesion

A class seeking certification under Rule 23(b)(2) "need not meet the additional predominance and superiority requirements of Rule 23(b)(3),*Gates v. Rohm and Haas Co*., 655 F.3d 255, 263-264 (3d Cir. 2011), but "it is well established that the class claims must be cohesive." *Barnes v. Am. Tobacco Co*., 161 F.3d 127, 143 (3d Cir. 1998). "Indeed, a (b)(2) class may require more

cohesiveness than a (b)(3) class." *Id*., at 142. The cohesion requirement is not wholly separate from the previous inquiry, because "when a court determines whether the defendant has acted or refused to act on grounds generally applicable to the class, the court is perforce examining whether the class is cohesive in nature." *Barnes v. American Tobacco Co*., 176 F.R.D. 479, 488 (E.D.Pa.1997), *aff'd*, 161 F.3d 127 (3d Cir.1998). "Rather, it is merely another way of stating that a class must be cohesive in order for a court to find that a defendant has acted on grounds generally applicable to the proposed class." *Agostino v. Quest Diagnostics Inc*., 256 F.R.D. 437, 456 (D.N.J. 2009). Thus, our finding that Plaintiffs' claims are primarily injunctive or declaratory under Rule 23(b)(2) already supports a finding of sufficient cohesiveness. Because we are forging new ground in our holding that this type of medical monitoring claim is eligible for Rule 23(b)(2) certification, however, we will proceed with a rigorous analysis of cohesiveness.

The Third Circuit in *Gates* indicated approval of the district court's method of determining cohesiveness under Rule 23(b)(2), in which the court analyzed cohesiveness in the same manner as a court would consider predominance under Rule 23(b)(3). *Gates*, 655 F.3d at 265. This requires the court to "formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case." *In re Hydrogen Peroxide Antitrust Litig*., 552 F.3d 305, 311 (3d Cir. 2008), as amended (Jan. 16,

2009) (internal quotation omitted)." If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable." *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 172 (3d Cir. 2001), as amended (Oct. 16, 2001). To prevail on a medical monitoring claim in Pennsylvania, plaintiffs must prove:

> (1) exposure greater than normal background levels;
> (2) to a proven hazardous substance;
> (3) caused by the defendant's negligence;
> (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease;
> (5) a monitoring procedure exists that makes the early detection of the disease possible;
> (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and
> (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

Redland Soccer Club, 696 A.2d at 145–46. Plaintiffs have provided the Court with various examples of the common proof they intend to use to establish each element of the putative class medical monitoring claim. Defendants argue that the "proposed class is not cohesive because the elements of exposure, significant risk increase, negligence, and a different and reasonably necessary medical monitoring program cannot be proved with common evidence." (Doc. 67, p. 20).

We will start first with exposure. Defendants focus their arguments on Plaintiffs' burden to prove actual exposure rather than potential exposure. While this is undoubtedly true, the Court is concerned at this juncture not with whether

Plaintiffs *have* proven exposure, but whether the putative class *could* offer "common proof [that] would accurately reflect the exposure of individual members." *Gates*, 655 F.3d at 265. In that vein, this litigation is distinctive because the alleged exposure comes from only one experience shared by every class member – open-heart surgery in the presence of a contaminated 3T System. This requires consideration of individual class members, but only with regard to this one fact. The necessity of proving one threshold fact for each class member is certainly not significant or predominant in light of all of the other factual and legal issues common to the class.

The putative class claim is highly distinguishable from *Gates* where exposure varied based on time, activity level, age, sex, genetic make-up, work, travel, and recreational habits. 655 F.3d at 267. Even further, the realm of possible 3T Systems used with each class member's surgery is only eight (Doc. 60, Ex. CC), distinguishing this matter from *Barnes* where "[d]efendants manufactured hundreds of different types of cigarettes over the years." 161 F.3d at 135. We find that the common proof necessary to prove exposure is sufficiently cohesive for class certification.

Relatedly, we find that Plaintiffs have demonstrated that the putative class can offer common proof to demonstrate increased risk of contracting a latent disease. Plaintiffs provide research studies concluding that any patient who

underwent surgery in the presence of a 3T System is at risk for infection, evidence of the link between heater-cooler systems and NTM, and expert opinions. (Doc. 72 att. 1, 11-13). Again we reiterate that Plaintiffs are not tasked with proving their claims at this juncture, but with demonstrating that proof common to the class will predominate over individual issues at trial. We find that Plaintiffs have demonstrated their ability to do so by pointing to evidence that will connect an increased risk of NTM infection with all of the WellSpan and Hershey 3T Systems.

Defendants argue that Plaintiffs cannot establish a class-wide need for medical monitoring. (Doc. 67, pp. 26-29). In support, Defendants point to the fact that Plaintiffs' proposed medical monitoring regime requires individual evaluations of the patients. (Doc. 67, p. 28). This argument is illogical. Medical care will, of course, vary between individuals. The question before the Court is whether there is common proof that monitoring *at all* is reasonably necessary for each class member. To this end, Plaintiffs have provided ample research studies, expert opinions, and CDC notices that suggest that *all* patients exposed to the 3T System receive medical monitoring. (Doc. 72, att. 1, pp. 15-16). That particular medical procedures and monitoring will be performed differently on each member due to individualized medical differences is immaterial.

Defendants also argue that Plaintiffs cannot establish through common proof that the medical monitoring proposed is different from that recommended in the

absence of exposure. (Doc. 67, pp. 29-30). In support, Defendants argue that some of the medical monitoring measures are part of ordinary follow-up care for cardiac patients. (*Id*., at p. 29). It is unclear how this would implicate individual issues to defeat cohesion – the issue addressed in this argument is whether the proposed regime is different from ordinary care, an issue clearly capable of proof by common evidence demonstrating what qualifies as "ordinary care" and what qualifies as the reasonable medical monitoring regime.

Finally, Defendants argue that Plaintiffs' cannot submit common evidence to prove negligence. (Doc. 67, pp. 24-26). In Pennsylvania, "negligence is the absence of ordinary care that a reasonably prudent person would exercise in the same or similar circumstances." *Martin v. Evans*, 711 A2d 458, 461 (Pa. 1998). To demonstrate negligence, the putative class will have to present evidence of the Defendants' knowledge of the risk of NTM and their reaction to it. Defendants argue that the putative class will be unable to do so with common proof because the class members' surgeries ranged from 2011 to 2015. (Doc. 67, p. 25). Defendants argue that the "science regarding NTM transmission from heater-coolers evolved over this period, along with Defendants' knowledge of the potential risk and their reaction to it." (*Id*.). Rather, Defendants argue, "the evidence and analysis of negligence will differ depending on the date of surgery,

the knowledge of the risks at that time, and whether Defendants acted reasonably based on their contemporaneous knowledge. (*Id.*, at pp. 25-26).

We recognize Defendants' argument that their proof in defense of negligence will vary based on whether a class member had surgery at the beginning of the time period or at the end. However, this issue does not defeat cohesiveness for two reasons. First, Plaintiffs have offered proof and indicated their intention to prove that Defendants were negligent throughout the *entire* class period. This weakens the Defendants' claim that the negligence analysis will significantly differ depending on whether the class member underwent surgery before or after they first became aware of the risk of *M. chimaera*. Second, the time period of the putative class member surgeries is limited. It only encompasses a period of roughly four years. In light of all of the other common issues in this matter, the differences that may arise in the negligence analysis within this limited period do not defeat cohesiveness.

We have reviewed the extensive exhibits submitted by both the Plaintiffs and the Defendants and find that common proof will vastly predominate over individual issues in a class claim to establish the elements of medical monitoring. Indeed, this is very likely one of a very small subset of medical monitoring claims that is so lacking in individual issues. The individual member characteristics or actions will have no bearing on the merits of the class claims; the only

individualized issues distinguishing member from member is where they received surgery and when. We will therefore grant the Motion and certify the class and Count One pursuant to Rule 23(b)(2).

Regarding Count Two, plaintiffs seek a declaration that the 3T System was defective. Whether Plaintiffs ultimately proceed under a design defect, manufacturing defect, or failure to warn defect theory, the proof of the claim depends on the Defendants' actions and knowledge and the product itself. It does not depend on any individualized evidence concerning each class member. Defendants argue that proof of a negligence-based design defect precludes class cohesiveness because "the science and Defendants' knowledge changed from 2011-2015." (Doc. 67, p. 31). We reject Defendants' argument for the same reasons that we find individualized issues do not preclude cohesion with regard to the negligence element of medical monitoring. Therefore we will also grant the Motion with regards to Count Two.

From a practical standpoint, we note that it will actually be to the Defendants benefit for the class to be certified. Defendants have strongly opposed the Motion for class certification, but in doing so they seem to elevate form over substance. Realistically, presenting one consolidated defense against all medical monitoring claims arising out of the use of the 3T Systems at Hershey and WellSpan will save time and resources for the Defendants. The alternative is to

face potentially thousands of individual medical monitoring claims, accumulating significant costs, all for the sake of presenting a virtually identical defense in each case.

IV. CONCLUSION

In light of the foregoing, we shall grant the motion for class certification. Plaintiffs have demonstrated that the putative class meets all requirements of Rule 23(a) and fits within Rule 23(b)(2). Further, judicial economy is served well by certification of the class. The evidence needed to prove the medical monitoring and declaratory judgment claims against the Defendants would be substantially the same for all putative class members. Class certification allows for both parties to conserve resources and efficiently resolve the factual and legal issues presented by the 3T System and NTM outbreak.

NOW, THEREFORE, IT IS HEREBY ORDERED THAT:

1. Plaintiffs' motion for class certification (Doc. 60) is **GRANTED**.

    a. The class is hereby defined as follows:

    > All individuals who underwent open heart surgery at WellSpan York Hospital between October 1, 2011 and July 24, 2015 or at Penn State Milton S. Hershey Medical Center between November 5, 2011 and November 5, 2015 and who are currently asymptomatic for NTM infection.

    b. Count I for medical monitoring is certified as a class claim to the extent that it seeks relief through a common fund financed by the

Defendants. It is not certified to the extent that it seeks any individualized damages or costs. Count II for declaratory judgment is also certified as a class claim.

c. Plaintiffs Edward Baker and Jack Miller are hereby designated as the class representatives.

d. Sol H. Weiss, Esq., and David S. Senoff, Esq., of Anapol Weiss and William M. Audet, Esq. of Audet & Partners, LLP are hereby appointed as class counsel.

2. Within thirty (30) days of the date of this Order, Plaintiffs shall file a motion for approval of their proposed forms of class notice and their notice program. ("Notice Motion). If the Notice Motion is opposed by any party, that party shall file a brief in opposition to the Notice Motion no later than fourteen (14) days after the filing of the Notice Motion.

3. Defendants' motion for oral argument (Doc. 70) is **DENIED**.

s/ John E. Jones III
John E. Jones III
U.S. District Judge